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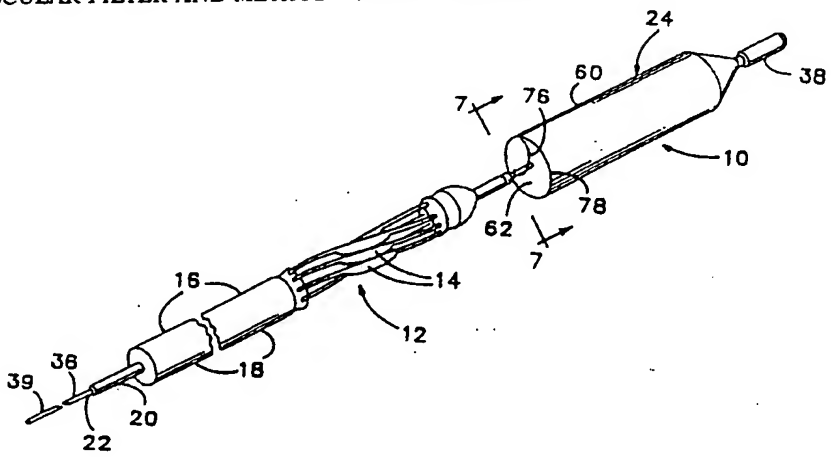
(54) Title: ENDOVASCULAR FILTER AND METHOD FOR USE THEREOF



(57) Abstract

A filter (10) useful in tubular organs of the human body, intended primarily for endovascular use during surgical procedures for removal of plaque and other treatment of stenoses in arteries, in order to entrap particles of plaque or other materials freed from the interior wall of an artery (30) while permitting continued flow of blood through the artery (30) during the procedure of treating the stenosis. Several filter elements (40, 42, 44, 46, 48, 50, 52, 54) are fastened in spaced-apart relationship with one another along a flexible elongate member and are large enough to require the entire flow of blood through the artery to pass through the filter elements (40, 42, 44, 46, 48, 50, 52, 54). An open-mouthed tubular stocking (60) of porous filter material encloses the filter elements (40, 42, 44, 46, 48, 50, 52, 54) and supports the periphery of each filter element. Successive filter elements (40, 42, 44, 46, 48, 50, 52, 54), progressing in the direction of blood flow, pass only progressively smaller particles. In a preferred embodiment, the mouth of the stocking (60) can be closed to retain particles of material within the filter as it is withdrawn from the artery (30) after repair of a stenosis.

* See back of page

ENDOVASCULAR FILTER AND METHOD FOR USE THEREOF

TECHNICAL FIELD

The present invention relates to filtration of fluid flow in tubular bodily organs, such as arterial and venous bloodstreams and the urinary tract, and particularly to a filter device for use during angioplasty and atherectomy procedures for relief of stenoses.

BACKGROUND ART

Occlusion of arteries by deposition of plaque or by thrombosis ultimately results in lack of sufficient blood flow to tissues served by the occluded artery, and eventually may result in necrosis. Patency of the lumen of an artery may be restored by different procedures including angioplasty and atherectomy, but these procedures may dislodge pieces of plaque or blood clots large enough to cause dangerous occlusion of smaller downstream vessels.

It is important not to have pieces of material such as plaque or blood clots significantly larger than blood cells moving freely in circulation in the blood vessels because of the danger of such particles lodging in a location which would interrupt the blood circulation to critical tissues such as heart muscle, brain tissue, etc.

Procedures in which foreign objects such as catheters are introduced into blood vessels may result in the formation of clots which might ultimately be released into the bloodstream. It is thus important in such procedures to prevent movement of dislodged blood clots or plaque and the like, and to capture and retrieve such pieces of material from within the blood vessel as a part of the completion of such procedures.

Various devices are known for the purpose of cutting or abrading plaque material from the interior lining of arteries. Their use has usually been

release particles of plaque into the bloodstream, and the device appears likely to allow flow of unfiltered blood when it is located in a portion of a blood vessel with an irregularly or asymmetrically shaped lumen.

Clark, III, U.S. Patent No. 3,996,938 discloses a cylindrical mesh tube with its opposite ends attached respectively to a tube and a central wire within the tube, so that relative movement of the wire and tube results in radial expansion and longitudinal contraction of the mesh material. The mesh material acts as a filter in order to remove a blood clot from within a blood vessel.

Luther U.S. Patent No. 4,650,466 discloses a device somewhat similar to that shown in the Clark, III, patent but intended to be used for abrading plaque from an arterial wall and not to filter blood.

What is needed, then, is a device able to prevent downstream transport of materials significantly larger than blood cells, as well as a method for its use to permit the flow of blood to continue during a procedure, such as angioplasty or atherectomy to correct a stenotic condition in a blood vessel. Such a device preferably should be able to capture debris and permit retrieval of the debris without pieces of debris being released into the bloodstream, either during use or as a result of retrieval. Additionally, the device should be able to be configured small enough to pass a stenosis in an artery, yet be dependably expandable, to peripherally coapt completely with an irregular vessel wall, to fill the lumen of the artery at a location downstream from a stenosis, so that the entire bloodstream through the artery is filtered. Such a device also needs to be effective at a location where a branch diverts from the main stem of blood vessel at a location downstream of a stenosis being treated.

Occasionally, initiation of filter removal must be preceded by initial withdrawal of the filter assembly still in an extended condition so that the vessel walls between the stenosis repair site and the location of the filter during the procedure can be "swept" clean of any debris that might have pooled or clung to that section.

Mechanisms are provided in the filter apparatus both to close the entrance to the filter and to refurl the filter elements and tubular stocking, to capture and realign the loose flaps and reduce the diameter of the filter stocking for safe withdrawal through access site sheaths.

In a preferred embodiment at least one drawstring is connected with the mouth of the stocking. In one embodiment of the device the drawstrings support the stocking, and through it support the filter elements to hold them generally transverse to the length of the artery. The drawstring or drawstrings are also useful to close the mouth of the stocking to retain trapped particles within the stocking during retrieval of the filter from its operative position within an artery.

In a preferred embodiment of the invention the filter elements and stocking are selectively controllable and movable with respect to the slender flexible support member, between a furled, reduced-diameter configuration and the larger-diameter operative configuration.

In a preferred embodiment of the invention the mouth of the stocking is selectively closeable to contain particles collected from the bloodstream during the course of a procedure to correct a stenosis, so that those particles are retained during removal of the filter device from its position in the artery.

In one embodiment of the invention several filter elements have different maximum pore sizes. The elements having larger pore sizes are located closer to the mouth of the stocking portion of the filter assembly, while the stocking itself and the filter elements further

materials which have been filtered from a stream of blood, so that the materials can be removed from a blood vessel with minimal danger of being released into the stream of blood during the procedure of removing the filter device from the blood vessels.

An important feature of the present invention is that it provides for filtration through filter media with successive stages having progressively smaller maximum pore sizes, in order to prevent early stoppage of the filter media.

A further important feature of the filter catheter of the present invention is the ability to "sweep" the walls of the vessel while still open to capture pooled or clinging debris where fluid flow is inadequate or non-existent.

Another important feature of the present invention is the provision of a drawstring closure to enclose pieces of material which have been filtered from the flow of blood.

The foregoing and other objectives, features, and advantages of the invention will be more readily understood upon consideration of the following detailed description of the invention, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an endovascular filter device embodying the present invention, together with a catheter atherotome with which the filter device is useful.

FIG. 2 is a sectional view of a portion of an artery in which the endovascular filter device shown in FIG. 1 is in use.

FIG. 3 is a view showing one filter element and supporting flexible ribs, taken along line 3-3 of FIG. 2.

FIG. 4 is a partially cut-away view of the filter element shown in FIG. 3.

arranged for introduction into a tubular organ in a direction opposite the normal direction of fluid flow therein.

FIG. 16 is a view of an opener useful for urging outward the ribs of a filter spreader element.

FIG. 17 is a view of the opener shown in FIG. 16, together with a portion of a filter element spreader, with the spreader in a position for urging the filter element toward a reduced-diameter, or closed, configuration.

FIG. 18 is a fragmentary detail view of the opener and portion of a spreader element shown in FIG. 17, with the opener moved to a position in which it urges the rib of the spreader element toward an outwardly expanded, or open configuration.

FIG. 19 is a side elevational view of a filter device which is another embodiment of the present invention.

FIG. 20 is a partially cut-away side view of a proximal end portion of a two-stage guide wire including a locking mechanism and intended particularly for use in carrying a filter device according to the present invention.

FIG. 21 is a view taken in the direction indicated by the line 21-21 of FIG. 20 showing the angular position locking aspect of the mechanism shown in FIG. 20.

BEST MODE FOR CARRYING OUT THE INVENTION

Referring now to the drawings, in FIG. 1 a filter device 10 embodying the present invention is shown together with a catheter atherotome 12 which includes a plurality of sharp-edged cutter blades 14 carried adjustably on a catheter assembly 16 including an outer tube 18 and an inner tube 20. The catheter atherotome may be similar to that disclosed in pending U.S. patent

diameter portion 56 of the elongate support member 36 and extend radially outwardly from the reduced diameter portion 56 in a generally circular, conical or arcuately curved configuration with each filter element disposed generally transverse to the reduced diameter portion 56. Each of the filter elements includes a respective peripheral portion 58 (FIG. 4), which is securely and tightly fastened, as by an adhesive or thermal weld, to the interior of a tubular stocking 60 of flexible filter material, which extends concentrically along the reduced diameter portion 56, defining a mouth 62 (FIG. 1), which opens generally toward the proximal end 39.

Referring now also to FIGS. 3 and 4, the filter element 54, which is representative of all of the filter elements, is shown at an enlarged scale. Each of the several filter elements 42, 44, 46, 48, 50, 52, and 54 is preferably made of a porous membranous material. To the extent possible, each filter element has pores of substantially uniform size, but each filter element is of a filter material having a different pore size. The pore size of the filter element 40 is smallest, and each successively more proximally located one of the filter elements has larger pores, thus permitting passage of larger particles of material through the filter element 54 than through the filter element 52. The maximum size of particles able to pass through each of the successive filter elements thus is progressively smaller in each successive filter element in the direction in which blood must flow through the filter assembly 24, as is shown in Table I below.

TABLE I

Filter Element (Reference Numeral)	40	42	44	46	48	50	52	54	60
Maximum opening size (microns)	20	30	40	50	60	70	80	100	20

In order to close the mouth 62 of the stocking 60 when desired, a drawstring 76 is attached to the marginal portion 78 defining the mouth 62 of the stocking 60, as by loops 77, as shown in FIG. 7, for example. The drawstring 76 extends about the entire circumference of the mouth 62, with an end 79 of the drawstring being attached to the stocking 60 as at 81. Thence, the drawstring 76 continues radially inwardly, extending spirally about the reduced diameter portion 56 and through into an opening 80 defined in a collar fitting 82 defining the proximal end of the reduced diameter portion 56, and into a lumen 83 defined within the guide wire 36. As a result, when the drawstring 76 is pulled in the direction indicated by the arrow 84 shown in FIG. 5, the marginal portion 78 of the stocking 60 is drawn radially inwardly and spirally along the reduced diameter portion 56 toward the proximal end 39. This both reduces the opening provided by the mouth 62 and twists the entire stocking 60, as well as the respective filter elements, progressively about the reduced diameter portion 56, to achieve the configuration shown in FIG. 8, resembling an umbrella folded and furled about its handle.

The drawstring 76 extends through the lumen 83 defined in the guide wire 36 to the proximal end 39 and may selectively be moved longitudinally with respect to the outer portion of the guide wire 36 to control the distension or closing of the stocking 60 and filter elements 54, 52, etc. of the filter device 10.

In the embodiment of the filter device 10 shown in FIGS. 1-12 the drawstring 76 is of a resiliently flexible material having abrasion resistance and high tensile strength, for example wire, which has some inherent stiffness and tendency to become straight and thus open the mouth 62 when the drawstring 76 is pushed or when tension in it is relieved. This is intended to avoid the possibility of the marginal portion 78 of the stocking 60 folding inward against the reduced diameter

through an opening 92 formed for the purpose, preferably percutaneously. The stocking 60 and filter elements 40, 42 etc. are furled tightly to the configuration shown in FIG. 9, so that the filter assembly 24 has a reduced diameter, and the guide wire 36 is utilized to push the filter assembly 24 through the artery 90 to the location of a stenosis 94 where an atherectomy procedure is to be performed. Led by the flexible tip 38, the filter assembly 24 is pushed through the stenosis 94 as indicated by the arrow 96 in FIG. 9, to a location a distance downstream from the stenosis 94, as shown in FIG. 10. The location of the filter assembly 24 at any particular time may be monitored by conventional means which need not be described here.

When the filter assembly 24 has been placed sufficiently far beyond the stenosis 94, the stocking 60 and filter elements 42, 44, etc. are deployed to fill the lumen of the artery 90 by relieving the tension in the drawstring 76, permitting it to move distally with respect to the guide wire 36. The mouth 62 is then opened as a result of the resiliency of the drawstring 76 as it slides through the loops 77, located along the marginal portion 78, attempting to increase the radius of curvature of the drawstring 76. Additionally, in a preferred embodiment of the filter assembly the resilient outwardly urgent bias of the radial ribs 66 of the spreader elements 64 helps to open each filter element 40, 42, etc., having an associated spreader element 64. Once the mouth 62 has opened appreciably the flow of blood into the interior of the stocking 60 may also aid in opening the filter assembly 24 into position to prevent material from flowing downstream beyond the filter assembly 24 except for having first passed through each of the filter elements.

Once the filter device 10 has been deployed to the condition shown in FIGS. 2 and 11, the proximal end 39 is threaded through the catheter atherotome 12 so that

76, retains the pieces of material such as the pieces 98 and 100 of plaque which had been cut free from the interior of the arterial wall, while the filter assembly 24 is then removed as indicated by the arrow 104 in FIG. 11. Because the lumen of the artery 90 has been enlarged within the stenosis 94, the filter assembly 24, even with a somewhat greater diameter than that of its original furled configuration as shown in FIG. 9, can pass outward through the artery 90 to be removed through the opening 92 by which it was introduced into the artery 90.

At times during a procedure including the use of the filter device 10, the flow of blood through the artery being treated may be monitored, as by the use of a stethoscope, by blood pressure measurements, or other non-invasive techniques appropriate to the particular artery concerned.

Although it is preferred to treat the filter device 10 or the patient, or both, with an appropriate chemical compound such as heparin or streptokinase, to prevent undesired clotting of blood within the filter device 10, it will be recognized that clotting may occur in the filter device 10, and that it may be necessary to withdraw the catheter atherotome 12 and subsequently the filter device 10, in response to observed loss of blood flow downstream of the filter device 10 subsequent to the beginning of an atherectomy procedure. Ordinarily, however, it should be possible to observe the increase in flow of blood to tissue downstream of the filter 10 as use of the catheter atherotome improves the patency of the artery 90.

Referring to FIGS. 13 and 14, an alternative embodiment of the invention includes a filter assembly 110 associated with a guide wire 112 including an outer tube 114 with an end fitting 116, with a plurality (such as 6, for example) of flexible tension supports 118 extending from the end fitting 116 to a mouth 120 of a stocking 122 otherwise similar to the stocking 60. A

Upon completion of the procedure and after removal of a catheter atherotome or other device used within a blood vessel upstream from the filter apparatus 110, the filter apparatus 110 can be prepared for removal by again moving the center wire 124 distally as indicated by the arrow 128 in FIG. 13, while preferably also rotating the center wire 128 with respect to the outer tube 114 to twist the stocking 122 and the flexible tension support members 118 into a helical, furled configuration resulting in a minimum diameter of the furled stocking 122, together with materials trapped within the filter device 110 during its withdrawal from the blood vessel where it has been used.

With the center wire 124 extending distally relative to the outer tube 114 as indicated by the arrow 128 in FIG. 13, the filter stocking 122 is held inward alongside the center wire 124. Preferably, the center wire 124 is also rotated with respect to the outer tube 114, so that the flexible tension supports 118 pull the stocking 122 into a helical, furled configuration fitting tightly about the center wire 124, as shown in FIG. 13, to provide a slender configuration of the filter assembly 110 to aid in insertion through a blood vessel.

As shown in FIG. 15, a suitable filter device 150 according to the invention may also be made for insertion into a vessel such as an artery from a location downstream from a location where a procedure to be performed might result in dislodgment of particles of material which should not be permitted to escape into the flow of blood and potentially be carried to locations where the particles might harmfully obstruct smaller branches of the vessel. The filter device 150 as shown in FIG. 15, includes a flexible tip 152 on a core or center wire 154 which is movable relative to an outer sheath member 156 to which is attached a filter material stocking 158 similar to the stockings 60 and 122. Also attached to the outer sheath 156, within the stocking

to the position shown in FIG. 18, in which the respective ribs 184 are urged outwardly by the opener 180 as a result of relative movement of the inner core member and the opener 180. This can be accomplished, for example, if the opener 180 is located in the position of the end fitting 116 of the filter assembly 110, in order to open a mouth portion of a filter stocking such as the filter stocking 122.

As may be seen in FIG. 19, a filter assembly 190 which is another embodiment of the invention includes a tubular stocking 192 having a closed distal end 194 attached to a flexible tip 196 of a two stage guide wire, but is without the additional filter elements used in the filter assembly as shown in FIGS. 2 and 14. An openable and closeable mouth 198 is attached to an end fitting 200 by tension-bearing closure members such as drawstrings 202 and is attached to the outer member 204 of the guide wire, whose smaller-diameter inner member 206 extends longitudinally through the interior of the stocking 192 to the guide wire tip 196. Preferably, there is a spreader element 208 similar to the spreader element 186, and the end fitting 200 includes the features of the opener 180 described hereinabove.

Referring now also to FIGS. 20 and 21, the proximal end portion of the guide wire of a filter assembly such as the filter assembly 190 may include a multi-position detent combination. In such a detent combination, the inner, or core portion 206 of the two-stage guide wire carries thereon a suitable number of radially outwardly extending annular detent collars 210 at predetermined positions along the length of the core member 206 at the proximal end of the guide wire.

The outer member 204 of the guide wire defines a lumen 212 whose size is sufficient to receive the detent collars slidably therein. A pair of inwardly protruding resilient locking rings 214 are located within the lumen 212, close enough to each other to receive and

WHAT IS CLAIMED IS:

1. An endovascular filter device, comprising:

(a) a slender flexible elongate support member having a proximal end and a distal end adapted for insertion into and along the interior of a blood vessel; and

(b) a filter assembly including:

(i) plurality of flexible filter elements attached to a portion of said elongate member and spaced apart from one another therealong adjacent said distal end;

(ii) a flexible tubular porous stocking surrounding said filter elements and interconnected with each of them, said stocking having a mouth directed generally toward said proximal end of said elongate member; and

(iii) means for supporting said tubular stocking with said mouth open to receive a flow of blood and with said filter elements in a flow-receiving and filtering position within said blood vessel.

2. The device of claim 1, including means associated with said stocking for selectively closing said mouth.

3. The filter device of claim 1 wherein each of said filter elements extends radially about said elongate support member and is attached thereto so as not to be movable longitudinally therealong, each of said filter elements having a periphery and said periphery of

8. The device of claim 1 including a plurality of drawstrings arranged for coordinated application of tension thereto for drawing said stocking and said filter elements into a furled configuration.

9. The device of claim 1 wherein said elongate flexible support member is a guide wire and includes a flexible tip portion extending distally beyond all of said filter elements.

10. The device of claim 9 wherein said guide wire has a reduced diameter portion to which said filter elements are attached, said tip portion being larger in diameter than reduced diameter portion.

11. The device of claim 1 wherein at least one of said plurality of filter elements is generally conical.

12. The device of claim 1 including a set of flexible resilient ribs extending radially from said flexible elongate support member adjacent one of said filter elements so as to urge said filter element toward a radially extended configuration.

13. The device of claim 12 wherein said elongate support member includes first and second parts, and at least one tension support extending between and being interconnected with both the mouth of said stocking and said first part of said elongate support member, and said stocking having a distal end attached to said second part of said elongate support member, said second part being movable, between a first position, in which said tension support is sufficiently slackened to allow said resilient ribs to move a respective one of said filter elements toward said radially extending configuration, and a second position, in which said stocking and said

17. The device of claim 16, including detent means for retaining said inner core wire in a desired location with respect to said outer member.

18. A method of relieving a stenosis in an artery, comprising:

(a) providing an endovascular filter device including a plurality of flexible filter elements attached to an elongate flexible guide wire and surrounded by a tubular stocking of flexible filter medium attached to said filter elements;

(b) forming an opening in an artery in a location proximal of a stenosis and inserting said guide wire into said artery through said opening, with said filter elements and said stocking in a furled configuration;

(c) extending said filter device into said artery until said filter elements and stocking have passed through and a predetermined distance beyond a stenotic portion of said artery;

(d) thereafter unfurling said stocking and filter elements so as to deploy said filter elements across the interior of said artery;

(e) thereafter enlarging the lumen of said artery by freeing pieces of material from the stenotic portion of said artery; and

(f) entrapping said pieces of material thus freed from said stenotic portion within said stocking.

19. The method of claim 18, including the further steps of closing said stocking so as to retain said pieces of material within said stocking, and

further from said distal end of said flexible elongate member.

28. The device of claim 24 wherein said stocking is of a filter medium substantially preventing passage of particles which are larger than a predetermined size.

29. The device of claim 24 wherein said means for selectively closing said mouth includes a drawstring attached to said stocking and extending along said elongate flexible support member toward said distal end thereof.

30. The device of claim 24 including a plurality of drawstrings arranged for coordinated application of tension thereto for drawing said stocking and said filter elements into a furled configuration.

31. The device of claim 24 wherein said elongate flexible support member is a guide wire and includes a flexible tip portion extending distally beyond all of said filter elements.

32. The device of claim 31 wherein said guide wire has a reduced diameter portion to which said filter elements are attached, said tip portion being larger in diameter than reduced diameter portion.

33. The device of claim 24 including a set of flexible resilient ribs extending radially from said flexible elongate support member adjacent one of said filter elements so as to urge said filter element toward a radially extended configuration.

along the interior of a blood vessel and a flexible tubular porous stocking surrounding a portion of said elongate support member, the stocking having a mouth directed generally toward said distal end of said elongate member, as well as a closed end surrounding said elongate member and located more proximally along said elongate member than the location of said mouth, and means for supporting said tubular stocking with said mouth open to receive a flow of blood;

(b) forming an opening in a blood vessel in a location downstream of a stenotic portion thereof by reference to the normal flow of blood, and inserting said flexible elongate support member into said blood vessel through said opening, with said stocking in a furled configuration;

(c) extending said filter device into said blood vessel until said stocking has approached to within a predetermined distance from said stenotic portion on a downstream side of said stenotic portion of said blood vessel;

(d) thereafter unfurling said stocking so as to deploy said stocking within said blood vessel with said mouth of said stocking substantially in intimate contact with the interior of said blood vessel;

(e) thereafter enlarging the lumen of said blood vessel by freeing pieces of material from said stenotic portion thereof; and

(f) entrapping within said stocking said pieces of material thus freed from said stenotic portion.

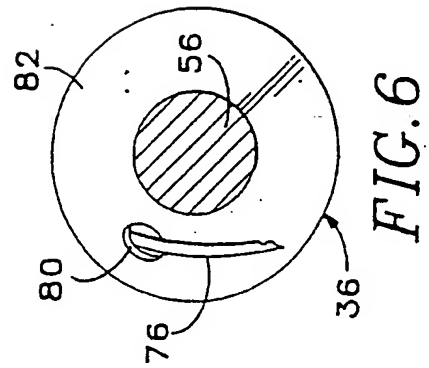


FIG. 6

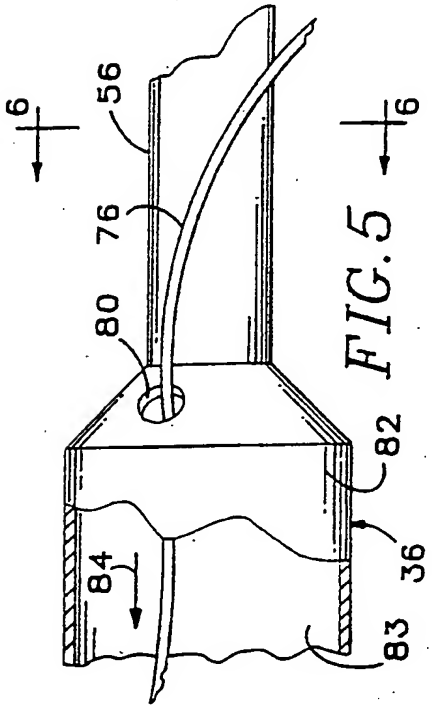


FIG. 5

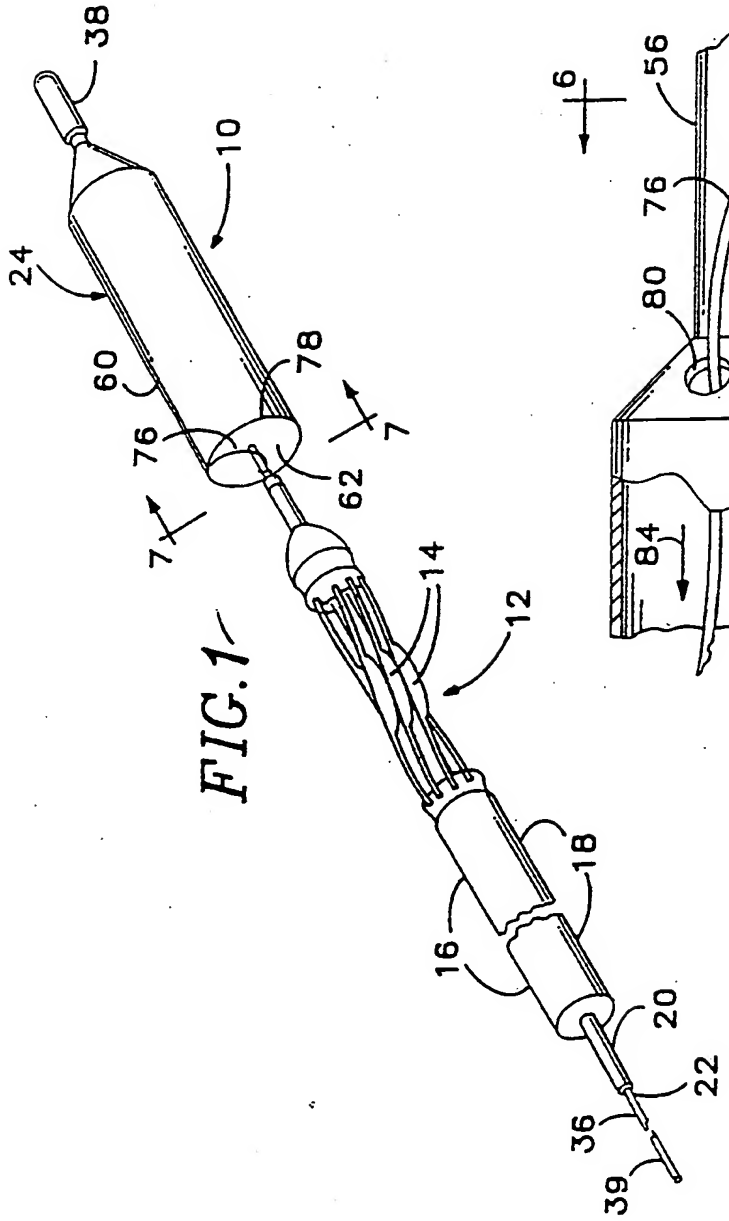
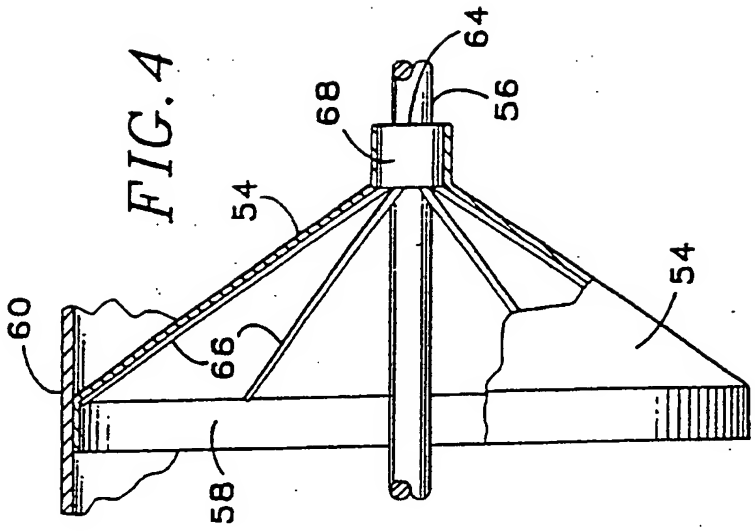


FIG. 1

FIG. 4



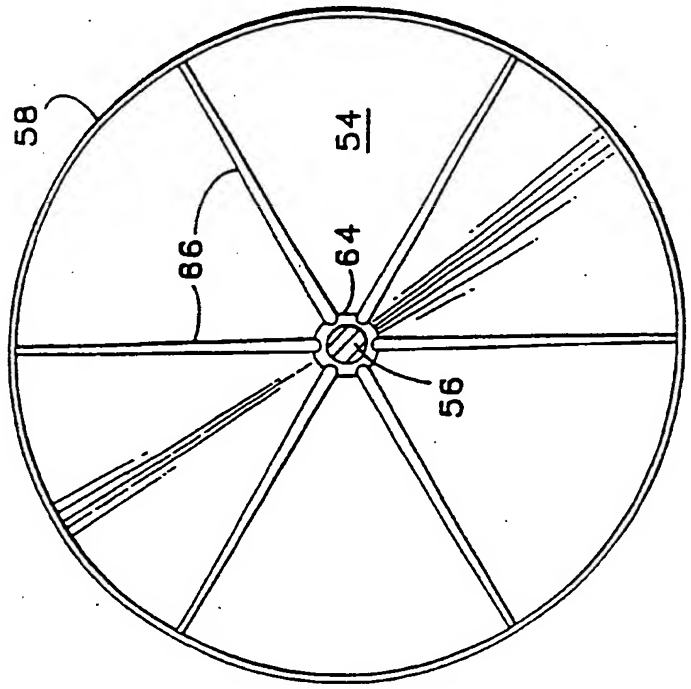


FIG. 3

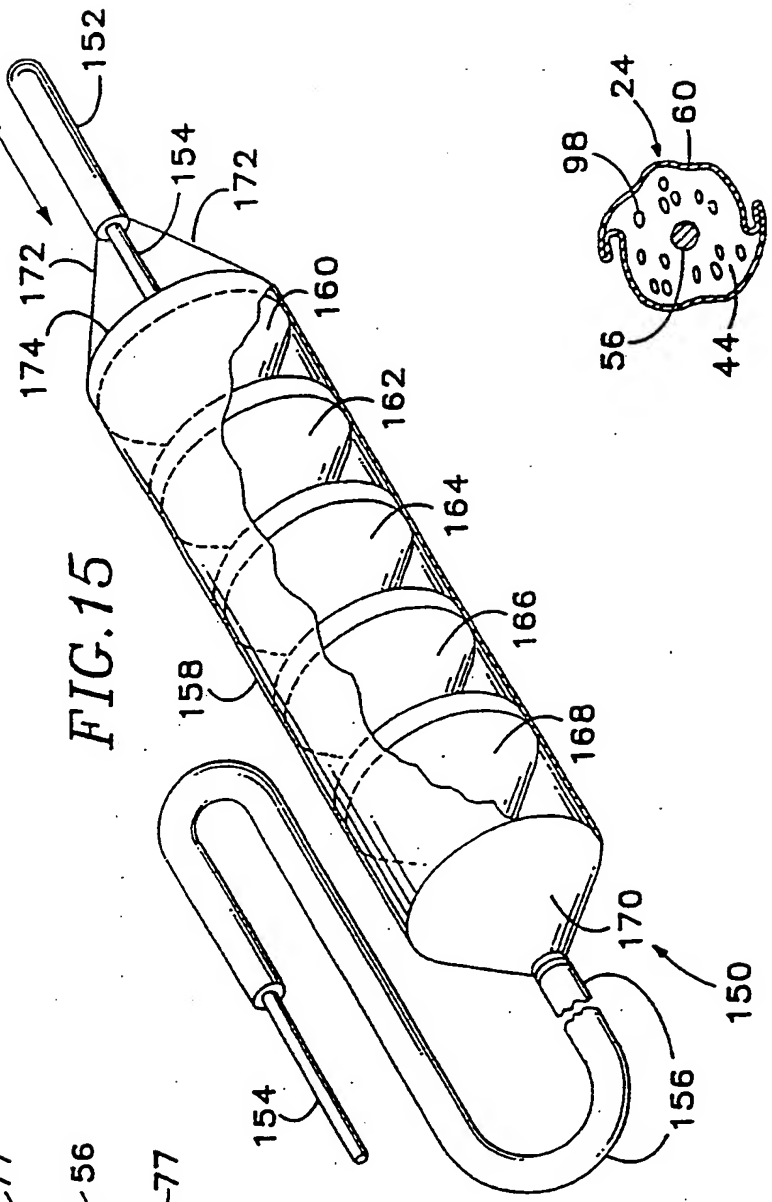


FIG. 15

FIG. 12

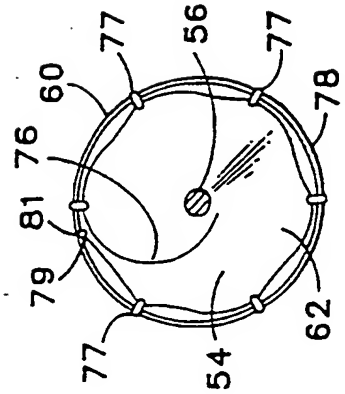


FIG. 7

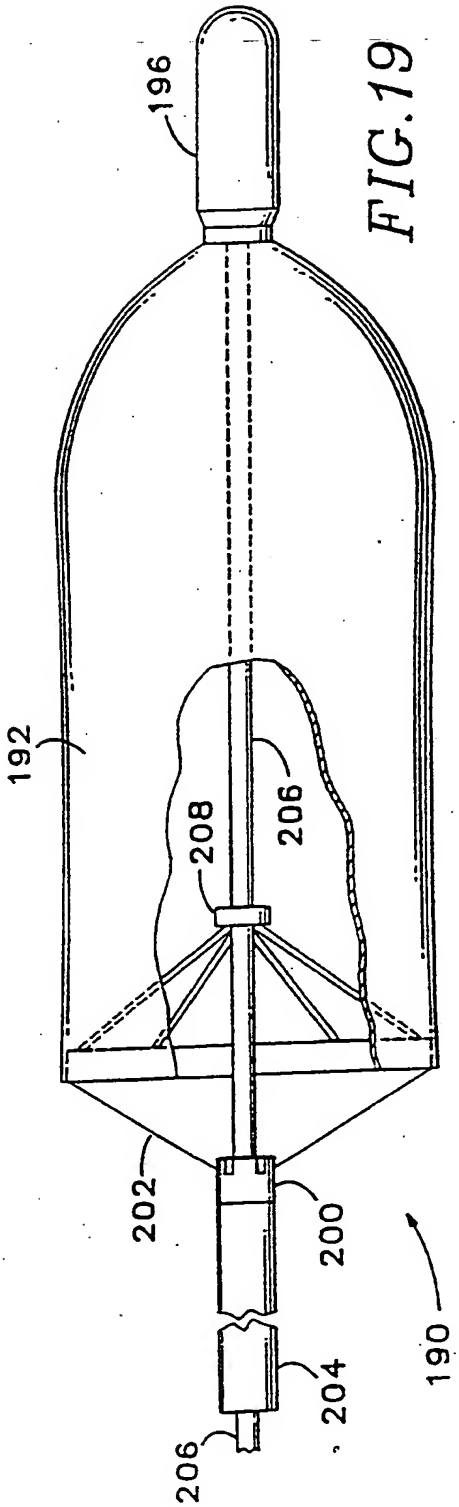


FIG. 19

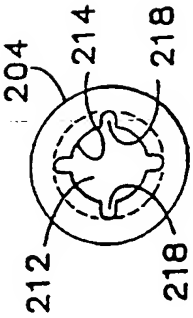


FIG. 21

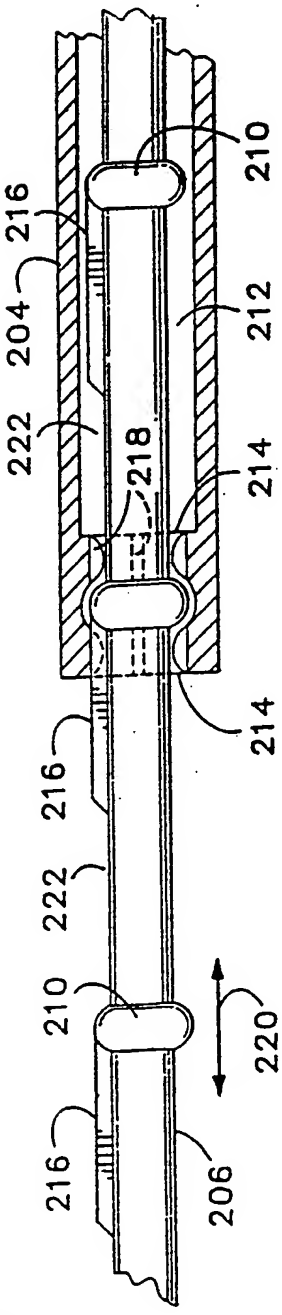


FIG. 20